DEC 3 0 2003

K033250

510(k) Summary

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, California 92614 USA
Contact:	Jason Smith, Senior Regulatory Affairs Specialist Phone: 949-250-2662 Fax: 949-250-3579 E-mail: jason_smith@edwards.com
Date Prepared:	October 3, 2003
Trade Name:	Edwards Lifesciences Vantex Central Venous Catheters with Thermistor (abbreviated to VCVC-T)
Common Name:	Intravascular Therapeutic Short-Term Catheter (21 CFR 880.5200)
Predicate Devices:	Edwards Lifesciences Vantex Central Venous Catheters with Oligon material Edwards Lifesciences Swan-Ganz True-Size Thermodilution Catheters.
Device Description:	The VCVC-T are used to access the central vein, infuse solutions, take blood samples, measure central venous temperature, and monitor central venous pressures.
Indications for Use:	The VCVC-T are indicated for use in patients requiring administration of solutions, blood sampling, temperature monitoring, and central venous pressure monitoring.
Comparative Analysis:	The VCVC-T add a new intended use (temperature monitoring) compared to the Vantex Central Venous Catheters. It accomplishes this new use by a different lumen configuration (3 infusion lumens, 1 thermistor lumen, and 1 isolation lumen), the addition of a thermistor, and a larger diameter than the Vantex Central Venous Catheters. The VCVC-T also has a new material, a potting material used to secure the thermistor at its distal end.

Functional/Safety Testing:	The VCVC-T have successfully undergone functional and biocompatibility testing.
Conclusion:	The VCVC-T are substantially equivalent to the predicate devices.

Jason Smith 10/31/03

Jason Smith
Senior Regulatory Affairs Specialist
Edwards Lifesciences LLC

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2003

Mr. Jason Smith
Senior Regulatory Affairs
Edwards Lifesciences LLC
One Edward Way
Irvine, California 92614

Re: K033250
Trade/Device Name: Edwards Lifesciences Vantex Central Venous Catheters with Thermistor
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: October 6, 2003
Received: October 7, 2003

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Viola Hibbard for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033250

Device Name: Edwards Lifesciences Vantex Central Venous Catheters with Thermistor

Indications For Use:

The Edwards Lifesciences Vantex Central Venous Catheters with Thermistor are indicated for use in patients requiring administration of solutions, blood sampling, temperature monitoring, and central venous pressure monitoring.

Patricia Cucenite

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K033250

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)